

## **REMARKS**

### **1. Amendments to the Claims**

As noted by the Examiner, the claims as filed were written in “use” format, taken from the European PCT application. These claims have been amended to properly be in US-style “method of treatment” format.

### **2. Response to Restriction Requirement**

The Examiner has required a restriction between the claims of Group I (claims 1-9), Group II (claims 10, 11 and 14), and Group III (claims 12-13 and 15-16). This requirement is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner has urged that the restriction requirement is proper because the claims allegedly do not relate to a common general inventive concept. Applicants submit that the Examiner’s position is improper because the claims do indeed contain a common general inventive concept which is neither anticipated nor made obvious by Ebner et al. (U.S. Patent 6,479,254 B2) referred to in the Office Action.

The present invention relates to a method of treating cancer specifically with activated DCs. The DCs according to the present invention have been loaded with an antigen against a specific tumor and treated with a combination of LPS and IFN-gamma so that they release IL-12 in a way that successfully enables tumor treatment.

Ebner et al. teaches the use of human AIM II to treat lymphadenopathy, rheumatoid arthritis, autoimmune disease and graft versus host disease (column 3, lines 22-30). With respect to the treatment of tumor cell growth (column 25, lines 22 ff.) the examiner specifically mentions that AIM II is suggested to be used as a direct AIM II protein treatment for tumor or non-tumor bearing mice. The examiner interprets this passage as “further teach pre-loading tumor or non-tumor bearing mice with tumor antigen”. This is, however, not a “loading of DCs with an antigen against a specific tumor” according to the present invention.

Moreover, in column 25, lines 27-30 of Ebner et al. the combination of AIM II protein with IL-12 is suggested to result in a synergistic or additive effect. This relates to the combination of the protein molecules AIM II and IL-12 in a pharmaceutical preparation.

In contrast thereto, according to the present invention DCs are loaded with a specific tumor antigen and treated with LPS and IFN-gamma, so that tumor antigen specific DCs release IL-12. These activated DCs are then administered to the tumor patient according to the present invention. This essentially differs from the therapeutic concept of Ebner et al., where AIM II protein and IL-12 protein are administered as such, i.e. as protein, to the patient.

The passage in column 57 which the examiner relates to with respect to IL-12 response relates to an in vitro assay for measuring IL-12 release of dendritic cells which have been treated with AIM II and LPS. Treatment of DCs with LPS, however, is also appreciated as prior art according to the present invention (see for example page 1, last paragraph, and page 2, 1st paragraph of the present specification).

In contrast to these prior art teachings, the present invention achieves a spectacular amplification of IL-12 release by the combined stimulation of tumor antigen loaded DCs with LPS and interferon gamma. This is neither disclosed nor made obvious in Ebner et al. nor in the documents discussed during international phase of the present application. Accordingly, novelty and inventive step were accepted for the claims as amended during the international phase. This common inventive concept of treatment of DCs with a combination of LPS and IFN-gamma does not belong to the prior art and accordingly the Restriction Requirement is not justified.

In view of the above reconsideration and withdrawal of the restriction requirement are requested, so that all the claims should be substantively examined in this application.

If, however, the Examiner nevertheless maintains the restriction requirement, then Applicants provisionally elect, with traverse, to prosecute the claims of Group II, namely claims 1-9.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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